HAND DELIVERED PATENT APPLICATION DOCKET NO.: 3276.1000-000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Johannes Gerdes, Thomas Scholzen, Elmar Endl, Claudia Wohlenberg,

Bettina Baron-Luhr, Margrit Kernbach né Hahn, Patricia Prilla, Johanna Suwinski

and Rolf Knippers

Application No.: 09/937,649

Group Art Unit: 1644

371 (c) Date:

January 28, 2002

Examiner: Haddad, M.

Confirmation No.: 2383

Title:

MONOCLONAL ANTIBODIES AGAINST HUMAN PROTEIN MCM3,

PROCESS FOR THEIR PRODUCTION, AND THEIR USE

HAND DELIVERED

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:	
This I	Information Disclosure Statement is submitted: under 37 CFR 1.129(a), or (First/Second submission after Final Rejection)
[]	under 37 CFR 1.97(b), or (Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
[]	under 37 CFR 1.97(c) together with either:
	[] a Statement under 37 CFR 1.97(e), as checked below, or
	[] a \$180.00 fee under 37 CFR 1.17(p), or (After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
[X]	under 37 CFR 1.97(d) together with:
	[X] a Statement under 37 CFR 1.97(e), as checked below, and
	[X] a \$180.00 fee under 37 CFR 1.17(p), or (Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
[]	under 37 CFR 1.97(i): Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper. (Filed after payment of issue fee)

State	ment U	nder 37	CFR 1.97(e)
[]	any c	ommun	information contained in this Information Disclosure Statement was first cited in ication from a foreign patent office in a counterpart foreign application not more onths prior to the filing of this Information Disclosure Statement; or
[X]	comm know in the	nunicati dedge of inform	on from a foreign patent office in a counterpart foreign application, and, to the file undersigned, after making reasonable inquiry, no item of information contained ation disclosure statement was known to any individual designated in 37 CFR than three months prior to the filing of this Information Disclosure Statement.
<u>State</u>	ment Ui	nder 37	CFR 1.704(d) (Patent Term Adjustment) Applies to original applications (other than design) filed on or after May 29, 2000
[]	comn was n	nunicati ot recei	information contained in the Information Disclosure Statement was cited in a on from a foreign patent office in a counterpart application and this communication ved by any individual designated in § 1.56(c) more than thirty days prior to the information Disclosure Statement.
[X]	Enclo	sed her	ewith is form PTO-1449:
	[X]	Copie	s of the cited references AD-AE are enclosed.
		[]	Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
	[]	Appli	s of the cited references are enclosed except those entered in prior application, U.S. cation No. [], to which priority under 35 U.S.C. 120 is claimed. [The earlier ation contains copies of the cited references.]
	[]	The li	sted references were cited in the enclosed International Search Report in a erpart foreign application.
	[]	The "o	concise explanation" requirement (non-English references) for reference(s) [37 CFR 1.98(a)(3) is satisfied by:
		[]	the explanation provided on the attached sheet.
		[]	the explanation provided in the Specification.
		[]	submission of the enclosed International Search Report.
		[]	submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
		[]	the enclosed English language abstract.

[]	A	pplic	cant requests that the following t	non-published pending applic	cations be considered:
Examiner Initials	's				
			U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []
	_		U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []
	-		U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []
			Examiner	Date	_
	[]	A copy of each above-cited app	olication, including the curre	nt claims, is enclosed.
	[]	A copy of each above-cited app those entered in prior application 35 U.S.C. 120 is claimed.	olication, including the curre on, U.S. Application No. [nt claims, is enclosed, excep], to which priority unde
The E	xar nce	niner s we	r is requested to return a copy of re considered with the next offic	the above list of pending appear communication.	plications indicating which
It is re	qu	ested	that the information disclosed h	erein be made of record in the	nis application.
Metho	od c	of pay	yment:		
[X]			ck for the fee noted above is encipanying Reply. A copy of this S		cluded in the check with the
[]	P er	lease nclos	charge Deposit Account 08-038 ed.	30 in the amount of [].	A copy of this Statement is
[X]	P	lease	charge any deficiency in fees an	nd credit any overpayment to	Deposit Account 08-0380.
			F	Respectfully submitted,	
			F	HAMILTON, BROOK, SMI	ΓΗ & REYNOLDS, P.C.
			E	Helen Lee Registration No.: 39,270 Telephone: (978) 341-0036 Facsimile: (978) 341-0136	

Concord, MA 01742-9133 Dated: Gether 15, 2103

HAMILTON BROOK SMITH & REYNOLDS, P.C.

PATENTS, TRADEMARKS COPYRIGHTS & LITIGATION

530 VIRGINIA ROAD P.O. BOX 9133 CONCORD, MA 01742-9133 TEL (978) 341-0036 FAX (978) 341-0136 www.hbsr.com

> MUNROE H. HAMILTON (1906-1984)

DAVID E. BROOK
JAMES M. SMITH
LEO R. REYNOLDS
JOHN L. DUPRÉ
DAVID J. BRODY
MARY LOU WAKIMURA
ALICE O. CARROLL
N. SCOTT PIERCE
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MARK B. SOLOMON
TROY T. SVIHL
A. CHISTINA TAYLOR*
DARRELL L. WONG
JOSEPH C. ZUCCHERO
NOT ADMITTED IN MASS.

OF COUNSEL ELIZABETH W. MATA

PATENT AGENTS
SUSAN M. ABELLEIRA
JESSE A. FECKER
PAMELA A. TORPEY
KAREN J. TOWNSEND
ROBERT H. UNDERWOOD

TECHNOLOGY SPECIALISTS
ALEXANDER AKHIEZER
PAUL G. ALLOWAY
KRAIG ANDERSON
LUCY LUBASHEV
VIVIEN J. TANNOCH
MICHAEL M. YAMAUCHI

MICHAEL KEWESHAN ADMINISTRATIVE DIRECTOR

BARBARA J. FORGUE ADMINISTRATOR OF PATENT AND THADEMARK PRACTICE

HAND DELIVERED

October 15, 2003

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Re: A

Appellants:

Johannes Gerdes, et al.

Application No.: 09/937,649

Confirmation No.: 2383

Title: Monoclonal Antibodies Against Human Protein MCM3,

Process for Their Production, and Their Use

Docket No.:

3276.1000-000

Sir:

Pursuant to a request by Examiner Haddad, Applicants are transmitting herewith copies of the Information Disclosure Statement, Form PTO-1449, and references AL-AZ, AL2-AZ2, AL3-AM3, AR3-AZ3, AR4-AZ4, and AR5-AY5, which were filed on February 22, 2002. Also transmitted herewith is a copy of the postcard receipt indicating receipt of the Information Disclosure Statement, Form PTO-1449 and references cited therein by the United States Patent and Trademark Office on February 22, 2002.

Please charge any deficiency or credit any overpayment in the fees that may be due in this matter to Deposit Account No. 08-0380. A copy of this letter is enclosed for accounting purposes.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

371(c) Date: January 28, 2002

Helen Lee

By All

Registration No.: 39,270 Telephone: (978) 341-0036 Facsimile: (978) 341-0136 Initiala: DEB/HL/saj

Nõ.: 3276.1000-000

Date: 2/15/02

This is to acknowledge receipt of the following documents each filed under Certificate of Mailing Procedure 37 C.F.R. 1.8:

	INFORMATION DISCLOSURE	STANEME	NT	w/copy	
<u>x</u> .	Form PTO-1449 pp _ 5	<u> </u>	th reference	s as noted in 1449	
	Check for \$				
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	Other	13 18	[77]		
Applic	ants: Johannes Gerdes et al.		10 sp		
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Date received by the PTO:





HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

530 VERGINIA ROAD P.O. BOX 9133 GONGORD, MASSACHUSETTS -01742-9133

25.

EXHIBIT

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PATENT APPLICATION DOCKET NO.: 3276.1000-000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Арр	licants:	Johannes Gerdes, Thomas Scholzen, Elmar Endl, Claudia Wohlenberg, Bettina Baron-Luhr, Margrit Kernbach né Hahn, Patricia Prilla, Johanna Suwinski and Rolf Knippers
Appl	ication No.:	09/937,649
371 ((c) Date:	January 28, 2002
Title	:	MONOCLONAL ANTIBODIES AGAINST HUMAN PROTEIN MCM3, PROCESS FOR THEIR PRODUCTION, AND THEIR USE
		CERTIFICATE OF MAILING I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C. 20231 on Date Signature Typed or printed name of person signing certificate
[] under 37 CFR (First/Second submis [X] under 37 CFR (Within any one of the stage in an internation CPA, or a Reduest for [] under 37 CFR [] a \$180. (After the 37 CFR 1.9) [] under 37 CFR [] a \$180. (Filed after final action) [] under 37 CFR	INFORMATION DISCLOSURE STATEMENT	
Thisl	under 37 CFR	osure Statement is submitted: 1.129(a), or on after Final Rejection)
[X]	(Within any one of the stage in an international	1.97(b), or following time periods: three months of filing national application (other than a CPA) or date of entry of the national application; or before the mailing date of a first office action on the merits in a non-provisional application, including a Continued Examination).
[]	under 37 CFR 1	.97(c) together with either:
		nent under 37 CFR 1.97(e), as checked below, or
		00 fee under 37 CFR 1.17(p), or (5) time period, but before final action or notice of allowance, whichever occurs first)
[]	under 37 CFR 1	.97(d) together with:
	[] a Statem	ent under 37 CFR 1.97(e), as checked below, and
		or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
[]	under 37 CFR 1 Applicant reques (Filed after payment of	ests that the IDS and cited reference(s) be placed in the application filewrapper.

State	ment L	Inder 3	7 CFR 1.97(e)
[]	any o	commu	of information contained in this Information Disclosure Statement was first cited in nication from a foreign patent office in a counterpart foreign application not more nonths prior to the filing of this Information Disclosure Statement; or
[]	com know in the	nunica vledge (e inform	information contained in this Information Disclosure Statement was cited in a tion from a foreign patent office in a counterpart foreign application, and, to the of the undersigned, after making reasonable inquiry, no item of information contained nation disclosure statement was known to any individual designated in 37 CFR than three months prior to the filing of this Information Disclosure Statement.
State	nent U	nder 37	(Patent Term Adjustment) Applies to original applications (other than design) filed on or after May 29, 2000
[]	comn was r	nunicat iot rece	f information contained in the Information Disclosure Statement was cited in a ion from a foreign patent office in a counterpart application and this communication ived by any individual designated in § 1.56(c) more than thirty days prior to the Information Disclosure Statement.
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	EHCIO	isec nei	rewith is form PTO-1449:
	[X]	Copie	es of the cited references are enclosed.
	ř]	- Appli	es of cited references are enclosed except those entered in prior application, U.S. cation No. [], to which priority under 35 U.S.C. 120 is claimed. [The earlier cation contains copies of the cited references.]
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	[]	The "e under	concise explanation" requirement (non-English references) for reference(s) [37 CFR 1.98(a)(3) is satisfied by:
		[]	the explanation provided on the attached sheet.
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		[]	submission of the enclosed International Search Report.
		[]	submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
		[]	the enclosed English language abstract.

[]	App	licant requests that the following	non-published pending	applications be considered:	
Examin Initials	er's				
	~	U.S. Patent Application No. [], by [inventor(s)], file	ed[], Docket No.:[]	
	_	U.S. Patent Application No. [], by [inventor(s)], file	ed[], Docket No.:[]	
	-	U.S. Patent Application No. [], by [inventor(s)], file	ed[], Docket No.: []	
		Examiner	Date		
	[]	A copy of each above-cited app	plication, including the c	urrent claims, is enclosed.	
	[]	A copy of each above-cited app those entered in prior application 35 U.S.C. 120 is claimed.			
The E	Examine ences we	er is requested to return a copy of ere considered with the next office	the above list of pending communication.	applications indicating whic	h
lt is r	equested	I that the information disclosed be	erein be made of record	in this application.	
Metho	od of pa	yment:			
]		ck for the fee noted above is enclo panying Reply. A copy of this Si		included in the check with th	e
]	Please enclos	charge Deposit Account 08-0380) in the amount of \$[]. A copy of this Statemen	t is
X]	Please	charge any deficiency in fees and	l credit any overpayment	to Deposit Account 08-0380	١.
		Ro	espectfully submitted,		
		HA	AMILTON, BROOK, SM	MITH & REYNOLDS, P.C.	
		Ву	Helen Lee Registration No.: 39,270 Telephone: (978) 341-0 Facsimile: (978) 341-0	036	

Concord, MA 01742-9133
Dated: Felmany (5, 2002

PTO-1449 REPRODUCED

INFORMATION DISCLO

ATTORNEY DOCKET No. 3276.1000-000

APPLICATION NO. 09/937,649

February 15,

(Use several sheets if necessary)

APPLICANT Johannes Gerdes et al.

371 (c) FILING DATE January 28, 2002 GROUP

TT C	בות אבו ויין על כו	DOCUMENTS

EXAM- INER INI- TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
mH	AA	5,223,409	29-JUN-1993	Ladner et al.	435	69.7	
mH	AB	4,816,567	28-MAR-1989	Cabilly et al.	530	387	
mH	AC	5,225,539	06-JUL-1993	Winter	530	387.3	
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	AE						
	AF						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CDASS	SUB- CLASS	TFANSI YES	ATION NC
mtt	AL	WO 92/18619	29-OCT-1992	PCT				
inst	AM	WO 91/17271	14-NOV-1991	PCT				
mH	AN	WO 92/20791	26-NOV-1992	PCT	ar ya yasan da s		_	
MIT	AO	WO 92/15679	17-SEPT-1992	PCT				
14	AP	WO 93/01288	21 <i>-J</i> AN-1993	PCT				
mit	ΑQ	WO 92/010147	23-JAN-1992	PCT				
мH	ALZ	WO 92/09690	11-JUNE-1992	PCT				
mt	AM2	WO 90/02809	22-MAR-1990	PCT				
mlt	AK2	WO 87/02671	07-MAY-1987	PCT				
MH	VOS	WO 86/01533	13-MAR-1986	PCT				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

intt	AR	Maine, G.T. et al., "Mutants of S. Cerevisiae Defective in the Maintenance of Minichromosomes," Genetics, 106:365-385 (1984).
mH	AS	Blow, J.J. and Laskey, R.A., "A Role for the Nuclear Envelope in Controlling DNA Replication Within the Cell Cycle," Nature, 332:546-548 (1988).
mtt	AT	Richter, A. and Knippers, R., "High-Molecular-Mass Complexes of Human Minichromosome-Maintenance Proteins in Mitotic Cells," Eux. J. Biochem., 247:136-141 (1997).

EXAMINER

Maker Haddad

DATE CONSIDERED 10/16/03

PT:0-14	49 REP	RODUCED		ATTORNEY DOCKET NO. APPLICATION NO. 09/937,649					
	IN	FORMATION DISCLOSURE IN AN APPLICATIO		APPLICANT Johannes Gerdes 6	et al.				
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mH	AP2	EP 0184187	11-JUN-1986	EPO	*****				
mH	AQ2	EP 0171496	19-FEB-1986	EPO ·					
mtt	353	EP 0173494	05-MAR-1986	EPO					
mH	АИ.3	EP 0125023	14-NOV-1984	EPO			<u> </u>		
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m#	עג		e Yeast Mcm3 1	ies of the Nuclear Replication Protein 992).				.an	
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mH	AH			"Continuous Cultur ined Specificity," .					
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in1+	AY	Cells Identified	by Immunopre	Antigers of Normal cipitation with Morenistry, 255(11):498	noclonal A	ocdian.			
nH	1.3	Yeh, M.Y. et al., "Cell Surface Antigens of Human Melanoma Identified by Monoclonal Antibody," Proc. Natl. Acad. Sci. USA, 75(5):2927-2931 (1979).							
mH	Yeh, M.Y. et al., "A Cell-Surface Antigen Which is Present in the Ganglioside Fraction and Shared by Human Melanomas," Int. J. Cancer, 29:269-275 (1982).								
mt	AS2			The Production of Mology Today, 4(3):			odies		
-т	Cole, S.P.C. et al., "The EBV-Hybridoma Technique and its Application								
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				Sheet 3 of 5	
PTC-1449 REPRODUCED			ATTORNEY DOCKET NO. 3276.1000-000	APPLICATION NO. 09/937,649	
INFORMATION DISCLOSURE CITATION IN AN APPLICATION			APPLICANT Johannes Gerdes et al.		
		February 15, 2002	371(c) FILING DATE	GROUP	
	(U	se several sheets if necessary)	January 28, 2002		
		OTHER DOCUMENTS (Including Autho	or, Títle, Date, Pertinent	Pages, Etc.)	
mt	AU2	Lerner, E.A., "How to Make a Hybridoma," The Yale Journal of Biology and Medicine, 54:387-402 (1981).			
mH	AV2	Gefter, M.L. et al., "A Simple Method for Polyethylene Glycol-Promoted Hybridization of Mouse Myeloma Cells," Somatic Cell Genetics, 3(2):231-236 (1977).			
ΜH	AW2	Galfre, G. et al., "Antibodies to Major Histocompatibility Antigens Produced by Hybrid Cell Lines," Nature, 266:550-552 (1977).			
mH	AX2	Fuchs, P. et al., "Targeting Recombinant Antibodies to the Surface of Escherichia Coli: Fusion to a Peptidoglycan Associated Lipoprotein," Bio/Technology, 9:1369-1372 (1991).			
m#	AY2	Hay, B.N. et al., "Bacteriophage Cloning and Escherichia Coli Expression of a Human IgM Fab," Hum. Antibod. Hybridomas, 3:81-85 (1992).			
mH	222	Ruse, W.D. et al., "Jeneration of a Large Combinatorial Library of the Immunoglobulin Repertoire in Phage Lambda," Science, 246:1275-1281 (1989).			
mH	ARB	Griffiths, A.D. et al., "Human Anti-Self Antibodies with High Specificity from Phage Display Libraries," The EMBO Journal, 12(2):725-734 (1993).			
mH	AS3	Hawkins, R.E. et al., "Selection of Phage Antibodies by Binding Affinity," J. Mol. Biol., 226:889-896 (1992).			
mtt	AT3	Clackson, T. et al., "Making Antibody Fragments Using Phage Display Libraries," Nature, 352:624-628 (1991).			
141	EUA	Gram, H. et al., "In Vitro Selection and Affinity Maturation of Antibodies from a Naive Combinatorial Immunoglobulin Library," Proc. Natl. Acad. Sci. USA, 89:3576-3580 (1992).			
mH	AV3	Garrard, L.J. et al., " F_{hg} Assembly and Enrichment in a Monovalent Phage Display System," Bio/Technology, 9:1373-1377 (1991).			
mH	EWA	Hoogenboom, H.R. et al., "Multi-subunit Proteins on the Surface of Filamentous Phage: Methodologies for Displaying Antibody (Fab) Heavy and Light Chains," Nucleic Acids Research, 19(15):4133-4137 (1991).			
mH	ANB	Barbas, C.F. et al., "Assembly of Combinatorial Antibody Libraries on Phage Surfaces: The Gene III Site," <i>Proc. Natl. Acad. Sci. USA,</i> 88:7978-7982 (1991).			
mH	AY3	Better, M. et al., "Escherichia Coli Secretion of an Active Chimeric Antibody Fragment," Science, 240:1041-1043 (1988).			
EXAMINER Maker Hoddad DATE CONSIDERED 16/16/03					

				Sheet 4 of 5
PTO-1949 XEPRODUCED			ATTORNEY DOCKET NO. 3276.1000-000	APPLICATION NO. 09/937,649
INFORMATION DISCLOSURE CITATION IN AN APPLICATION			APPLICANT Johannes Gerdes et al.	
February 15, 2002		February 15, 2002		
(Use several sheets if necessary)		•	January 28, 2002	GROUP
		OTHER DOCUMENTS (Including Authority	or, Title, Date, Pertinent	Pages, Etc.)
MH	AZ3	Liu, A.Y. et al., "Chimeric Mouse-Human IgG1 Antibody that can Mediate Lysis of Cancer Cells," Proc. Natl. Acad. Sci. USA, 84:3439-3443 (1987)		
mH	AR4	Liu, A.Y. et al., "Production of a Mouse-Human Chimeric Monoclonal Antibody to CD20 with Potent Fc-Dependent Biologic Activity," The Journal of Immunology, 139(10):3521-3526 (1987).		
mH	AS4	Sun, L.K. et al., "Chimeric Antibody with Human Constant Regions and Mouse Variable Regions Directed Against Carcinoma-Associated Antigen 17-1A," Proc. Natl. Acad. Sci. USA, 84:214-218 (1987).		
mH	AT4	Nishimura, Y. et al., "Recombinant Human-Mouse Chimeric Monoclonal Antibody Specific for Common Acute Lymphocytic Leukemia Antigen," Cancer Research, 47:999-1005 (1987).		
mH	AU4	Wood, C.R. et al., "The Synthesis and In Vivo Assembly of Functional Antibodies in Yeast," Nature, 314:446-449 (1985).		
тН	AV4	Shaw, D.R. et al., "Mouse/Human Chimeric Antibodies to a Tumor-Associated Antigen: Biologic Activity of the Four Human IgG Subclasses," Journal of the National Cancer Institute, 80(13):153-159 (1988).		
мн	AW4	Morrison, S.L., "Transfectomas Provide Novel Chimeric Antibodies," Science, 229:1202-1207 (1985).		
m fl	AX4	Di, V.T. et al., "Chimeric Antibodies," BioTechniques, 4(3):214-221 (1986).		
m#	AYA	Jones, P.T. et al., "Replacing the Complementarity-Determining Regions in a Human Antibody with those from a Mouse," Nature, 321:522-525 (1986).		
mH	3,24	Verhoeyen, M. <i>et al.</i> , "Reshaping Human Antibodies: Grafting an Antilysczyme Activity," <i>Science</i> , 239:1534-1535 (1988).		
rn H	AR5	Beidler, C.B. et al., "Cloning and High Level Expression of a Chimeric Antibody with Specificity for Human Carcinoembryonic Antigen," The Journal of Immunology, $141(11):4053-4060$ (1988).		
mH	ASS	Mashal, R.D. et al., "Expression of Cell Cycle-regulated Proteins in Prostate Cancer," Cancer Research, 56:4159-4163 (1996).		
mtt	AT'5	Toyoshima, H. et al., "p27, a Novel Inhibitor of Gl Cyclin-Cdk Protein Kinase Activity, is Related to p21," <i>Cell</i> , 78:67-74 (1994).		
ntl	AU5	Lloyd, R.V. et al., "Aberrant p27 ^{kipl} Expression in Endocrine and Other Tumors," American Journal of Pathology, 150(2):401-407 (1937).		
m H	AV5	Zhang, P. et al., "Cooperation Between the Cdk Inhibitors p27KIP1 and p57KIP2 in the Control of Tissue Growth and Development," Genes & Development, 12:3162-3167 (1998).		
EXAMINER DATE CONSIDERED Waker Haddad 10/16/03				

PTO-1449 REPRODUCED INFORMATION DISCLOSURE CITATION IN AN APPLICATION		RODUCED	ATTORNEY DOCKET NO. 3276.1000-000	APPLICATION NO. 09/937,649
			AFPLICANT	
	February 15, 2002		Johannes Gerdes et a	al.
	(U:	se several sheets if necessary)	371 (c) FILING DATE January 28, 2002	GROUP
		OTHER DOCUMENTS (Including Autho	pr, Title, Date, Pertinent	: Pages, Etc.)
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EXAMINER	Maher	Haddad
	Maner	Hodday